



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

September 18, 1997

97-PHI-42

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

McBride Dairy Farm  
Mont McBride, Partner  
Alan R. McBride, Partner  
Leslie M. McBride, Partner  
William McBride, Partner  
RD #1  
P.O. Box 376  
New Galilee, Pennsylvania 16141

10/1/97

434

GEN.	SPEC.
RELEASE	9/19/97
F#	DATE
Reviewed by: <i>[Signature]</i>	

Dear Mr. McBride:

An inspection of your farm, located on RD #1 in Enon Valley, Pennsylvania, conducted by Food and Drug Administration (FDA) investigator Robert Vaughn on July 23, and August 1, and 13, 1997, confirmed that you offered a cow for sale for slaughter for human food in March 1997 in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 24, 1997, you offered a cow, ear tag #23DKJ1906, for slaughter as human food at [REDACTED]. The animal was slaughtered by [REDACTED] on or about March 24, 1997. United States Department of Agriculture (USDA) testing of the animal revealed the presence of the following violative antibiotic residues in the edible tissues of the animal.

<u>Tissue</u>	<u>Antibiotic Residue (ppm)</u> (parts per million)	<u>Tolerance</u> (ppm)
Liver	oxytetracycline - 10 ppm	6.00
	sulfadimethoxin - 5.2 ppm	0.1
Muscle	oxytetracycline - 44 ppm	2.00
	sulfadimethoxin - 7.5 ppm	0.1

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The above oxytetracycline and sulfadimethoxin tissue residues are considered to be an violative since the tolerance for oxytetracycline is 6.0 ppm for liver tissue and 2.0 ppm for muscle tissue and the tolerance for sulfadimethoxin is 0.1 ppm in edible bovine tissue. The presence of oxytetracycline and sulfadimethoxin in the liver and muscle tissues from your animal at the concentration levels detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that

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correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,



Diana J. Kolaitis  
District Director  
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director  
PA State Bureau of Animal Industry  
Agriculture Building  
2301 North Cameron Street  
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)  
106 South 15th Street  
Suite 904  
Omaha, Nebraska 68102  
Attention: Residue Staff

cc: Dr. F.R. Rellosa  
USDA Northeast Regional Office  
701 Market Street  
2B South  
Mellon Independence Center  
Philadelphia, PA 19102-1516